UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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TZUMI INNOVATIONS, LLC,

Plaintiff,

Civil Action No. 21-cv-00122-LGS

v.

ANDREW R. WHEELER, in his Official Capacity as Administrator of United States Environmental Protection Agency,

and

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Defendants.

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FIRST AMENDED VERIFIED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Tzumi Innovations, LLC ("Tzumi"), by way of this Complaint against the U.S. Environmental Protection Agency ("EPA") and Andrew R. Wheeler in his official capacity as Administrator, U.S. Environmental Protection Agency ("Administrator"), hereby states and alleges as follows:

NATURE OF THE ACTION

1. This action arises from the EPA's contention that a Tzumi product, "Wipe Out!" hand wipes, which is registered with the Federal Food and Drug Administration ("FDA") as an over-the-counter (OTC) drug for use on humans, should also be registered with the EPA as a "pesticide" under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §136 *et seq*.,

and its implementing regulations, 40 C.F.R. Part 150 *et seq*. ("FIFRA") based upon the product's label.

2. Because Tzumi's product is not registered with the EPA -- which gave no warning that contrary to years of custom and practice, hand sanitizing products would now have to be registered with the EPA -- the EPA is treating the product as an unregistered "pesticide," and on that basis demanded that Tzumi provide a plan to voluntarily recall some 9 million units of the "Wipe Out!" product in stores by January 8, 2021, failing which, the EPA threatened to issue a Stop Sale, Use, or Removal Order (a "SSURO").

3. Under FIFRA, the EPA regulates germicidal wipes intended for use on inanimate surfaces. It does not regulate germicidal wipes intended for use on human skin, which fall within the definition of a "drug" under the Federal Food, Drug and Cosmetic Act. The EPA has left regulation of that product to the FDA.

4. In reliance upon this longstanding and codified allocation of regulatory responsibility between the FDA and the EPA, Tzumi, with the help of a supplier experienced in the production of hand wipes for the American market, brought its "Wipe Out!" hand wipe product to market in September 2020, in compliance with the FDA's requirements for germicidal hand wipes. "Wipe Out!" is intended and labeled for use in killing germs on the hands and elsewhere on the person.

5. On or about September 1, 2020, the EPA e-mailed Tzumi and one of Tzumi's retailer distributors ("Retailer A") an "advisory letter" dated August 29, 2020, accusing Tzumi of: (a) selling and distributing unregistered and misbranded pesticides; (b) claiming the product was effective against viruses as well as bacteria; and (c) implying in the phrase "Use it Anytime,

Anywhere" that the product could be used on surfaces other than hands. The letter states that it is based on information discovered on [Retailer A's] website.

6. Tzumi then spent the next four months trying to learn the basis for the EPA's conclusion that these hand wipes are a pesticide rather than a drug. Prior to commencing this action, Tzumi's counsel repeatedly attempted to engage the EPA in substantive discussions regarding the Agency's concerns, initially by phone and then in correspondence dated December 6, 2020, December 14, 2020, and December 31, 2020.

7. Tzumi commenced this action by Verified Complaint and Order to Show Cause seeking a temporary restraining order and preliminary injunction on January 7, 2021.

8. At the Court's direction, the parties negotiated a standstill agreement to preserve the *status quo* and moot Tzumi's request for a temporary restraining order pending the Court's ruling on Tzumi's application for preliminary injunctive relief. The standstill agreement was entered as an Order of the Court on January 15, 2020. (ECF No. 22). Pursuant to the standstill agreement, the EPA agreed not to issue an SSURO to Tzumi for 40 days nor to any retailer without 7 days' notice that would allow renewal of Tzumi's TRO application. (Id.)

9. Other than the temporary relief afforded by the standstill agreement, the EPA has declined to engage in meaningful discussions with Tzumi, despite numerous detailed letters from Tzumi's counsel asking the Agency to reconsider its determination that "Wipe Out!" is a pesticide and requesting a meeting to discuss possible alternatives to a SSURO.

10. The EPA has not provided a reasoned explanation for the Agency's enforcement actions or its unwillingness to engage in substantive discussions regarding the application of FIFRA to FDA-regulated products.

11. The EPA has not identified any threat to human health or the environment posed by the "Wipe Out!" hand wipes product.

12. The EPA has provided no evidence that consumers will be induced to use the "Wipe Out!" hand wipes on inanimate surfaces because of the phrase "Use it Anytime, Anywhere."

13. The EPA has refused to consider curative measures for language on the label to which the EPA has objected.

14. The EPA has threatened to proceed with the SSURO or similar enforcement action to remove the "Wipe Out!" product from commerce.

15. Under these circumstances, the EPA's demand for a product recall plan and threatened issuance of a SSURO are unlawful under FIFRA and violate the Administrative Procedure Act ("APA") as arbitrary and capricious agency action, improper retroactive change of regulatory position without notice and a hearing, and illegal rulemaking.

16. The SSURO, or any other enforcement action that would have an impact or effect substantially similar to a SSURO, if implemented, will cause Tzumi to suffer more than $50 million of unrecoverable economic losses as well as permanent and irreparable reputational and goodwill damage.

17. Pursuant to FIFRA and the APA, Tzumi seeks declaratory and injunctive relief to deter the arbitrary and capricious actions of Defendants in demanding a product recall plan by a date certain and threatening a SSURO in lieu of a recall, without so much as a hearing to determine whether hand sanitizer products can be considered pesticides based on consumer use,

despite the existence of an Executive Order specifically precluding this type of unfair surprise. "Wipe Out!" hand wipes are not "pesticides" under the plain language of FIFRA and its regulations; Defendants have not identified any hazard to human health or the environment; and Defendants are breaking with longstanding regulatory practice without prior notice to the regulated community and an opportunity to be heard, all despite substantial reliance by Tzumi – and, on information and belief, other entities – on the longstanding practice of complying with FDA requirements for manufacturing and labeling hand sanitizing products.

PARTIES

18. Plaintiff Tzumi is a limited liability company organized under the laws of New York in 2017, with its principal place of business located at 16 East 34th Street, New York, NY, 10016.

19. Defendant EPA is headquartered at 1200 Pennsylvania Avenue, N.W., Washington, DC 20460, and also has offices in New York, New York.

20. Defendant Andrew R. Wheeler, Administrator of EPA, in his official capacity, has his office at 1200 Pennsylvania Avenue, N.W., Washington, DC 20460.

JURISDICTION AND VENUE

21. Jurisdiction over the parties and subject matter of this action are proper in this Court pursuant to 7 U.S.C. § 136n (final action of the Administrator not committed to the discretion of the Administrator by law), 28 U.S.C. § 1331 (actions arising under the laws of the United States), and 28 U.S.C. § 1346 (civil action against the United States founded on an Act of Congress or regulation of an executive agency).

22. The actions of the EPA challenged in this lawsuit constitute final agency action because the Agency has articulated an unequivocal position regarding the "Wipe Out!" product and expects Tzumi to alter its conduct to conform to that position.

23. An actionable and justiciable controversy between Tzumi and Defendants requires resolution by this Court.

24. This Court has personal jurisdiction over Defendants EPA and Administrator of EPA.

25. Venue in this district is proper pursuant to 28 U.S.C. § 1391(b) and (e) and 5 U.S.C. § 703.

STANDING

26. Plaintiff Tzumi has standing to bring this action under 5 U.S.C. § 702 as a person aggrieved by agency action.

27. Tzumi has exhausted all administrative remedies available to it. Tzumi has no administrative process to invoke to review the final agency actions of the EPA at issue.

FACTUAL BACKGROUND

A. The Plaintiff And The Product

28. Tzumi has approximately $18 million of net assets and $115 million of annual revenue.

29. Early in 2020, responding to the huge demand for hand sanitizing products, Tzumi began the process of bringing "Wipe Out!" hand wipes to market.

30. The product is a fabric wipe impregnated with 0.13% benzalkonium chloride in a pull-out cylindrical plastic container. That concentration of benzalkonium chloride is the industry standard for such hand wipes.

31. All the components of "Wipe Out!" were manufactured and assembled abroad by a supplier experienced in the production of hand wipes for the American market. The supplier advised Tzumi how to label the product to comply with the requirements of the FDA. The label was also reviewed and approved by Intertek Group plc ("Intertek"), a global and experienced quality assurance firm, in a detailed "artwork and labeling review" process that included analysis of font size and label content.

32. The label for "Wipe Out!" hand wipes at issue here states on the front of the canister, along with the name "WIPE OUT!," that the product "Kills 99.9% of Germs*" and "Kills Germs Fast" and that it contains "Antibacterial Wipes." The asterisk refers elsewhere on the label to the specific bacteria that the product kills: E. coli, Staph, and Candida Albicans. On the side, the label states that the product "Cleans and Sanitizes," "Use it Anytime, Anywhere," and "Safe on Hands." True and accurate copies of the artwork and labeling on the packaging of "Wipe Out!" hand wipes are attached as Exhibits 1A-1D to this Complaint ("Compl. Ex. 1").

33. The side panel also provides directions for disposing of the wipes. On the rear, the label sets forth the "Drug Facts" required by FDA regulations. This includes the active and inactive ingredients, directions for use and storage, the statement that the use of the product is "To decrease bacteria on the skin that could cause disease," and the warning that it is "For external use only." Nowhere does the label recommend or even refer to use on surfaces or to any use other than on hands. (See Compl. Ex. 1).

34. The ability of Tzumi hand wipes to kill 99.9% of particular bacteria was tested for safety and effectiveness by the independent, third-party authenticator noted *supra*, Intertek, which found that "Wipe Out!" hand wipes kill 99.9% of three specific bacteria. Intertek approved the Tzumi label, including the phrases "Use it Anytime, Anywhere" and "Kills 99.9% of Germs," on condition that the names of the specific bacteria killed by the product be added to the label, as they were.

35. Tzumi's labelling is typical of the industry for germicidal wipes. The phrase, "Use it Anytime, Anywhere," refers to the product's mobility. The canister can be taken anywhere and used anywhere, including outside the home as a substitute for liquid hand sanitizers.

B. Allocation of Regulatory Responsibility

36. When used on the human body, germicidal wipes are subject to exclusive regulation by the FDA under the Federal Food Drug and Cosmetic Act ("FFDCA"). The FDA designates such germicidal wipes intended for use on humans as "drugs" under the FFDCA.

37. The FFDCA defines a "drug," in pertinent part, to include "a substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease." 21 U.S.C. § 321(g)(1)(B).

38. Under FIFRA, the EPA regulates germicidal wipes as "pesticides" only when intended for use on inanimate surfaces.

39. Benzalkonium chloride prevents disease by killing micro-organisms and is thus a "drug" subject to FDA regulation.

40. The EPA enforces FIFRA, 7 U.S.C. § 136 *et seq.*, which regulates pesticides. FIFRA defines a "pesticide" to include substances that prevent, destroy, repel or mitigate any "pest." 7 U.S.C. § 136(u). It defines "pest" to include bacteria, except for bacteria on or in the human body. 7 U.S.C. § 136(t).

41. Because benzalkonium chloride kills micro-organisms, it is potentially a pesticide subject to EPA regulations when intended for use on inanimate surfaces.

42. The overlap between the two agencies' jurisdiction is resolved by FIFRA's definition of "pest," which excludes micro-organisms "on or in living man or other living animals." 7 U.S.C. § 136(t).

43. Reflecting the statute, an EPA regulation yields jurisdiction over drugs to the FDA by declaring that micro-organisms "in or on living man" are not "pests" under FIFRA. 40 C.F.R. § 152.6(c). The regulation provides:

> Fungi, bacteria, viruses or other microorganisms in or on living man are not "pests" as defined in section 2(t) of FIFRA. Products intended and labeled for use against such organisms are human drugs subject to regulation by the FDA under the FFDCA.

44. That regulation follows the definition in 7 U.S.C. § 136(t). It also implements the 1971 Memorandum of Understanding ("MOU") between the newly formed EPA and the former Department of Health Education and Welfare (currently Department of Health and Human Services), the FDA's parent agency.

45. The MOU declares that its purpose is to eliminate the "confusion, misunderstanding and inconvenience" arising from the fact that some products are subject to the

requirements of both the FFDCA and FIFRA. It gives the EPA jurisdiction over products intended for use on inanimate surfaces:

> 3(i) The application of a product for any of, but not necessarily limited to, the uses listed below is considered to be both a pesticide and human drug. The agency for primary jurisdiction regarding such products will be EPA and secondarily FDA.
>
> Disinfectants and sanitizers **intended for use on inanimate objects** but including claims for use on humans. [Id.] [Emphasis added].

46. Both agencies accept this division of responsibility, on which the regulated community has long relied.

47. In a Q&A on an EPA website, the EPA acknowledges that "[h]and sanitizers, antiseptic washes and antibacterial soaps are regulated by the Food and Drug Administration (FDA)."

> Q. Why aren't hand sanitizers listed on the EPA's List N (for coronavirus use)?
>
> A. List N includes only EPA-registered surface disinfectants. Hand sanitizers, antiseptic washes and antibacterial soaps are regulated by the Food and Drug Administration (FDA). EPA-registered surface disinfectants, including surface wipes, should not be applied on your skin or ingested. (Emphasis added.)

48. On a website entitled "Disposable Wipes," the FDA likewise recognizes this allocation of responsibility:

> Wipes intended for a therapeutic purpose, such as killing germs on the skin, or treating acne, diaper rash, or other skin conditions, are drugs under the law. Drugs must meet requirements for FDA approval for safety and effectiveness before they go on the market. Drugs are regulated by FDA's Center for Drug Evaluation and Research.
>
> Wipes intended to control germs on inanimate surfaces (disinfect or sanitize) and wipes containing insect repellents are regulated by the Environmental Protection Agency.

49. The Centers for Disease Control and Prevention (CDC), an HHS component agency, also recognizes this division of responsibility between the FDA and the EPA. According to the CDC, the EPA's registration requirement for substances intended to prevent, destroy, repel, or mitigate "pests" covers micro-organisms, such as bacteria or viruses, but excludes micro-organisms in or on living humans or animals.

C. Hand Wipes Containing Benzalkonium Chloride Are Regulated By The FDA

50. Because of the large volume of over-the-counter ("OTC") drug products, the FDA does not review and approve them individually. Instead, under the OTC Drug Review Process, it publishes in the Federal Register a "monograph" for each of 80 therapeutic classes of OTC drugs. For each category, the monograph is a kind of recipe book covering acceptable ingredients, doses, formulations, and labeling.

51. These monographs define the safety, effectiveness, and labeling of all OTC active ingredients.

52. Once a final monograph is implemented, companies can make and market an OTC product that complies with the monograph without FDA pre-approval of the particular product.

53. The FDA currently permits consumer antibacterial hand wipes that use benzalkonium chloride to be marketed pursuant to a 1994 monograph that governs antibacterial sanitizers in the health care context. See 59 FR 31402 (June 11, 1994).

D. Executive Order 13892 - Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication

54. On October 9, 2019, the President signed Executive Order 13892, 84 FR 55239, which provides in relevant part:

> Sec. 4. Fairness and Notice in Administrative Enforcement Actions and Adjudications. When an agency takes an administrative enforcement action, engages in adjudication, or otherwise makes a determination that has legal consequence for a person, it may apply only standards of conduct that have been publicly stated in a manner that would not cause unfair surprise. An agency must avoid unfair surprise not only when it imposes penalties but also whenever it adjudges past conduct to have violated the law.
>
> Sec. 5. Fairness and Notice in Jurisdictional Determinations. Any decision in an agency adjudication, administrative order, or agency document on which an agency relies to assert a new or expanded claim of jurisdiction—such as a claim to regulate a new subject matter or an explanation of a new basis for liability—must be published, either in full or by citation if publicly available, in the Federal Register (or on the portion of the agency's website that contains a single, searchable, indexed database of all guidance documents in effect) before the conduct over which jurisdiction is sought occurs.
>
> Sec. 6. Opportunity to Contest Agency Determination. (a) Except as provided in subsections (b) and (c) of this section, before an agency takes any action with respect to a particular person that has legal consequence for that person, including by issuing to such a person a no-action letter, notice of noncompliance, or other similar notice, the agency must afford that person an opportunity to be heard, in person or in writing, regarding the agency's proposed legal and factual determinations. The agency must respond in writing and articulate the basis for its action.
>
> (b) Subsection (a) of this section shall not apply to settlement negotiations between agencies and regulated parties, to notices of a prospective legal action, or to litigation before courts.
>
> (c) An agency may proceed without regard to subsection (a) of this section where necessary because of a serious threat to health, safety, or other emergency or where a statute specifically authorizes proceeding without a prior opportunity to be heard. Where an agency proceeds under this subsection, it nevertheless must afford any person an opportunity to be heard, in person or in writing, regarding the agency's legal determinations and respond in writing as soon as practicable. [Emphasis added].

E. The EPA Threatens Enforcement

55. If the EPA believes that an entity sells or distributes an unregistered pesticide in violation of FIFRA, the EPA has at its disposal a variety of informal and formal civil enforcement tools.

56. First, the EPA may simply warn the seller or distributor that it must register the product and seek a negotiated resolution.

57. Second, the EPA may seek civil monetary penalties against the alleged violator, upon a hearing after proper notice.

58. Third, under certain circumstances the EPA may seize the unregistered product.

59. Fourth, the EPA may issue a SSURO, which requires the seller or distributor to stop selling or using, or to remove, the product at issue. See FIFRA § 13, 7 U.S.C. §§ 136k.

60. Because SSUROs are such a severe sanction, the EPA's internal enforcement guidelines caution that they "are generally reserved for situations involving a potential hazard to health or the environment," and prior to issuing the SSURO, the EPA must "identify the violation and develop evidence to support the existence of a violation." See EPA FIFRA Inspection Manual, Chapter 14, p. 2.

61. On or about September 1, 2020, the EPA e-mailed Tzumi what it captioned as an "advisory letter," dated August 29, 2020, accusing Tzumi of: (a) selling and distributing unregistered and misbranded pesticides; (b) claiming the product was effective against viruses as well as bacteria; and (c) implying in the phrase on the label "Use it Anytime, Anywhere" that the product could be used on inanimate surfaces as well as hands. The letter stated that it was

"based on information discovered on [Retailer A's] website." A true and accurate copy of the EPA's letter to Tzumi dated August 29, 2020 is attached as Exhibit 2 to this Complaint. ("Compl. Ex. 2").

62. Despite its title, the EPA advisory letter was in no sense advisory. It was a command and a threat. It commanded Tzumi to remove all product in stores and dispose of product within its possession and control. (Compl. Ex. 2, at 2). It threatened that the EPA would assess penalties or would take "any other action authorized under FIFRA," which includes a stop-sale order served on stores, with the loss of goodwill that entails. (Id.).

63. The language on Retailer A's website that the EPA considered improper read as follows: "These all-purpose disposable wipes remove common allergens, germs and messes **on surfaces** like kitchen counters, bathroom **surfaces** and more." (Id.) (Emphasis added). A Tzumi employee drafted this language to be included in the product description on Retailer A's website, initially not realizing the description was inaccurate.

64. Prior to receiving the EPA's advisory letter on September 1, 2020, Tzumi concluded that the reference to surface use should be removed and was already taking steps to have that language removed from Retailer A's website.

65. Upon information and belief, all references to cleaning inanimate surfaces were removed from the "Wipe Out!" product description on Retailer A's website by the first week in September 2020.

66. Retailer A did not receive its first shipment of "Wipe Out!" until approximately September 1, 2020.

67. From early September 2020 forward, the marketing language for "Wipe Out!" hand wipes on Retailer A's website described the product as a "Hand Wipe" used to "[c]lean your hands with bleach-free wipes to keep dirt and germs away and leave behind a clean Fresh scent."

68. Counsel for Tzumi told EPA counsel that the marketing language on Retailer A's website was changed at Tzumi's request, but the EPA would not soften its stance, shifting its focus to the phrase on the label, "Use it Anytime, Anywhere."

69. The EPA has asked Tzumi to recall and destroy all FDA-registered hand wipe inventory bearing that phrase. This consists of approximately 9 million units already in stores and an additional 10 million units still within the possession and control of Tzumi.

70. On or about September 9, 2020, EPA pesticide enforcement staff member Kristin Ridarick called Tzumi to discuss the labelling of the "Wipe Out!" product.

71. In response, Tzumi sent the EPA its then-current label, the one on approximately 19 million units of "Wipe Out!" hand wipes at issue here, and attached hereto as Exhibits 1A to 1D.

72. In a September 10, 2020 e-mail, even though the label stated that the product was for use "on the skin" and "external use only," the EPA objected that the *front* of the label did not say the product was only for hands. The e-mail cites no statute or regulation that would require this language. A true and accurate copy of the EPA's September 10, 2020 e-mail is attached as Exhibit 3 to this Complaint. ("Compl. Ex. 3").

73. On September 15, 2020, at the request of the EPA, Tzumi sent EPA enforcement staff member Ridarick a proposed revised label, adding "HAND WIPES" on the front of the package and removing the suggestion "Use it Anytime, Anywhere." A true and accurate copy of Tzumi's September 15, 2020 e-mail is attached as Exhibit 4 to this Complaint. ("Compl. Ex. 4").

74. The EPA has not responded to this revised label other than to say in conversations with Tzumi's counsel that the EPA would not comment on the label.

75. Because of the EPA's reluctance to discuss this label, and in the absence of any regulation or other guidance from the EPA, Tzumi does not know whether the EPA would demand that Tzumi recall products bearing that revised label.

76. Telephone conversations between EPA counsel and Tzumi's counsel confirmed the EPA's concern with the phrase "Use it Anytime, Anywhere" and revealed the EPA's belief that the font size on the label stating that the product was to be used "to decrease bacteria on the skin" and is "For external use only" is too small.

77. The type size actually complies with both FDA and EPA standards. FDA regulations require 6-point type or larger for the drug facts, 21 C.F.R. § 201.66(d), and the size of the type on the "Wipe Out!" label is 8-point. Similarly, EPA regulations require 6-point type. 40 CFR 156.10(a)(2)(ii)(A).

78. On December 6, 2020, Tzumi's counsel, Thomas H. Prol, sent EPA counsel Jeannie Yu a detailed e-mail setting forth the extensive steps Tzumi took to market its "Wipe Out!" product as a hand sanitizer under FDA jurisdiction, including documentation of the extensive involvement of a third-party authenticator, Intertek. A true and accurate copy of the

December 6, 2020 e-mail is attached as Exhibit 1 to the Declaration of Thomas H. Prol ("Prol Declaration") (ECF No. 7).

79. On December 14, 2020, Mr. Prol sent Ms. Yu a supplemental letter following up on Mr. Prol's December 6, 2020 e-mail and reiterating Tzumi's request for substantive discussions with the EPA to address the Agency's concerns before the issuance of a SSURO. A true and accurate copy of Mr. Prol's December 14, 2020 letter is attached as Exhibit 2 to the Prol Declaration.

80. On December 17, 2020, Mr. Prol spoke on the telephone with Ms. Yu for approximately one-hour. During this conversation, Ms. Yu, on behalf of Defendants, demanded that Tzumi provide a plan for a voluntarily recall of the "Wipe Out!" product by January 8, 2021, failing which, the Defendants would issue a SSURO.

81. During the December 17, 2020 telephone call, Ms. Yu agreed to arrange for a meeting between Tzumi and EPA staff during the week of December 21, 2020. However, on December 21, 2020, Ms. Yu e-mailed Mr. Prol and rescinded the meeting offer, stating that in the Agency's opinion, a "meeting would be unproductive." A true and accurate copy of Ms. Yu's December 21, 2020 e-mail is attached as Exhibit 3 to the Prol Declaration.

82. On December 31, 2020, Mr. Prol again wrote to the EPA, pleading for the opportunity for Tzumi to present its case before the Agency. A true and accurate copy of Mr. Prol's December 31, 2020 letter is attached as Exhibit 4 to the Prol Declaration.

83. The EPA has not responded.

84. The EPA has demanded that Tzumi remove all units of "Wipe Out!" hand wipes with FDA-approved packaging from commerce on the ground that the product is a misbranded pesticide subject to FIFRA even though it is an FDA approved drug.

85. The EPA has refused to explain the legal basis for its conclusion that these hand wipes are a pesticide rather than a drug.

86. The EPA has provided no evidence that consumers will be induced to use the wipes on hard surfaces because of the phrase "Use it Anytime, Anywhere."

87. The EPA has shown no risk of harm to consumers or the environment from consumers' using hand wipes on inanimate surfaces.

88. The EPA has refused to consider curative measures for the label to which it has objected and has rejected Tzumi's request for an informal hearing in the form of a meeting with Tzumi's representatives.

89. Tzumi is left to speculate about what, if anything, it can do to satisfy the EPA that "Wipe Out!" hand wipes are a drug and not a pesticide.

90. The EPA's refusal to confer affects not only items already on store shelves but items under contract as well, which will bear a label revised in response to EPA requests.

91. Tzumi has contracts to supply approximately 10 million units of "Wipe Out!" hand wipes to retailers and does not know whether the EPA considers the product containing the revised label to be subject to FIFRA.

F. Tzumi Will Suffer Irreparable Injury From A Recall Or SSURO

92. Tzumi's losses because of the SSURO, or equivalent government action to remove "Wipe Out!" from the shelves, will be substantial. Its total U.S. market sales in 2020 were $115 million, with "Wipe Out!" sales accounting for $101 million of that amount. The annual sales from "Wipe Out!" were expected to be $80 million to $100 million in 2021.

93. Tzumi currently has 9 million units of "Wipe Out!" with the old label on the shelves with retailers that would be removed if the EPA is permitted to proceed with the SSURO.

94. Tzumi will lose between $350,000.00 and $500,000.00 per day if the SSURO is implemented.

95. In addition, Tzumi will lose the additional cost of approximately $400,000.00 per month in carrying unsold inventory.

96. The SSURO, if implemented, will cause Tzumi to suffer more than $50 million of unrecoverable economic losses as well as permanent and irreparable reputational and goodwill damage.

97. Also, stores may assert breach of sales contract claims against Tzumi, seeking to recoup their own lost investments in advertising expenses and lost sales.

98. The total damages caused by the SSURO will be even higher. Because of the highly competitive hand wipe market, the withdrawal of "Wipe Out!" will trigger a series of other irreparable economic impacts, such as unrecoverable losses of reputation and goodwill.

99. Tzumi sells "Wipe Out!" under its own name, and a recall will harm customer goodwill for the brand because people will assume that a product recalled by the EPA is unsafe.

100. It will also harm retailer goodwill because of the inconvenience and loss imposed on them by the recall.

101. Given the numerous alternatives in the market, retailers may not risk going back to a product the EPA has branded as unsafe, even if the Court ultimately decides this suit in Tzumi's favor.

COUNT I
Violation of Administrative Procedure Act
(EPA's Determination That "Wipe Out!" is a Pesticide is Arbitrary and Capricious and Contrary to Law)

102. Paragraphs 1 through 101 of this Complaint are incorporated by reference, and alleged, as though fully stated herein.

103. Tzumi has no administrative remedies to exhaust prior to making this claim. Tzumi has no administrative process to invoke to review the final agency actions of the EPA at issue.

104. The APA provides that a court in reviewing agency action "shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" and "without observance of procedure required by law." 5 U.S.C. § 706.

105. Where violations of federal law have occurred, the APA authorizes courts to issue injunctions or fashion other appropriate remedies to correct such violations. See 5 U.S.C. § 705.

106. FIFRA defines a "pest" to exclude microbes on or in the human body and a "pesticide" to mean a product intended to kill a "pest."

107. A finding that "Wipe Out!" is a "pesticide" is a basic jurisdictional element necessary to trigger the EPA's authority to regulate the product.

108. EPA's threatened enforcement action to remove "Wipe Out!" from commerce is arbitrary and capricious and otherwise not in accordance with law in violation of 5 U.S.C. § 706(2)(A) because "Wipe Out!" hand wipes are not pesticides as defined by FIFRA or its implementing regulations.

109. Specifically, EPA's conclusion that "Wipe Out!" hand wipes are a pesticide because of the phrase "Use it Anytime, Anywhere" or because consumers are allegedly using them to sanitize surfaces is arbitrary and capricious and contrary to law.

110. EPA's threatened enforcement action is arbitrary and capricious and otherwise not in accordance with law in violation of 5 U.S.C. § 706(2)(A) because the EPA has failed to provide a reasoned explanation for its conclusion that "Wipe Out!" is a pesticide, its demand for a recall plan, and its threat to remove the product from the market.

111. EPA's actions are "otherwise not in accordance with" FIFRA § 2(u); 7 U.S.C. 136(u) and 40 C.F.R. §§ 152.6 and 152.15(b) and are thus contrary to law.

COUNT II
Violation of Administrative Procedure Act
(EPA's Retroactive Change of Regulatory Position Without Notice and a Hearing, without an Articulated Rationale, and Despite Substantial Reliance by the Regulated Community on the Existing Regulatory Scheme is Arbitrary and Capricious and Contrary to Law)

112. Paragraphs 1 through 111 of this Complaint are incorporated by reference, and alleged, as though fully stated herein.

113. FIFRA defines a "pest" to exclude microbes on or in the human body and a pesticide to mean a product intended to kill a "pest." In accord with this statutory exclusion, hand sanitizing sprays and wipes have been regulated by the FDA for decades as a drug, not by the EPA as a pesticide. The agencies have a memorandum of understanding dividing their regulatory responsibility in that manner, and EPA regulations reflect that division.

114. With the onset of the pandemic, EPA has apparently now decided to regulate hand sanitizing products because, the EPA contends, consumers are using them to sanitize inanimate surfaces.

115. Manufacturers, distributors, and sellers, including Tzumi, produced millions of dollars of hand sanitizing products, registered them with the FDA, labeled them in compliance with FDA regulations, and distributed them to stores in reliance on decades of FDA and EPA regulatory policy.

116. The EPA has undertaken the foregoing change of regulatory direction without prior notice to the regulated community, without giving the members of that community an opportunity to be heard, without proposing a new regulation or even issuing a guidance, and without publishing a rationale for the change.

117. The EPA change of regulatory policy, if implemented retroactively, without prior notice, will require manufacturers, distributors and sellers to recall and destroy millions of dollars' worth of FDA-compliant hand sanitizing products and will expose them to penalties for violation of FIFRA.

118. The EPA has not explained how its change in regulatory policy serves the public interest protected by FIFRA or why the harm to reliance interests by applying the change retroactively is outweighed by the public interest protected by FIFRA.

119. Under these circumstances, the EPA's change of regulatory direction is arbitrary and capricious and violates the APA.

120. This is confirmed by the EPA's violation of E.O. 13892 (84 FR 55239), which, among other things, requires publication of changes in agency policy -- such as a claim to regulate new subject matter – to avoid surprise and to give the regulated industry a chance to comment.

COUNT III

Violation of the Administrative Procedure Act (Unlawful Rulemaking)

121. Paragraphs 1 through 120 of this Complaint are incorporated by reference, and alleged, as though fully stated herein.

122. EPA's attempt to change its interpretation of FIFRA and its own regulations regarding what constitutes intention that a product be used as a pesticide is unlawful because it does not comply with the notice and comment rulemaking procedures under the APA.

123. Instead, EPA enforcement procedure has led to the issuance of an immediately effective interpretation, giving the regulated community no prior notice and taking no input from that community; publishing no proposed rule nor a rationale for the change; and denying Tzumi and the rest of the regulated community time to come into compliance with the new regulatory approach.

124. EPA's actions constitute unlawful rulemaking in violation of the APA, 5 U.S.C. § 553.

125. Absent injunctive relief, Tzumi will be irreparably harmed. Injunctive relief will not harm the EPA, and it will serve the public interest not only by safeguarding the rulemaking procedure but also by making a useful hand sanitizing product available to consumers during the pandemic.

COUNT IV

Violation of Executive Order 13892 - Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication

126. Paragraphs 1 through 125 of this Complaint are incorporated by reference, and alleged, as though fully stated herein.

127. The EPA's attempt to regulate by enforcement violates Executive Order 13892, 84 FR 55239, (October 9, 2019), which provides in relevant part:

> Sec. 4. Fairness and Notice in Administrative Enforcement Actions and Adjudications. When an agency takes an administrative enforcement action, engages in adjudication, or otherwise makes a determination that has legal consequence for a person, it may apply only standards of conduct that have been publicly stated in a manner that would not cause unfair surprise. An agency must avoid unfair surprise not only when it imposes penalties but also whenever it adjudges past conduct to have violated the law.
>
> Sec. 5. Fairness and Notice in Jurisdictional Determinations. Any decision in an agency adjudication, administrative order, or agency document on which an agency relies to assert

a new or expanded claim of jurisdiction—such as a claim to regulate a new subject matter or an explanation of a new basis for liability—must be published, either in full or by citation if publicly available, in the Federal Register (or on the portion of the agency's website that contains a single, searchable, indexed database of all guidance documents in effect) before the conduct over which jurisdiction is sought occurs.

Sec. 6. Opportunity to Contest Agency Determination. (a) Except as provided in subsections (b) and (c) of this section, before an agency takes any action with respect to a particular person that has legal consequence for that person, including by issuing to such a person a no-action letter, notice of noncompliance, or other similar notice, the agency must afford that person an opportunity to be heard, in person or in writing, regarding the agency's proposed legal and factual determinations. The agency must respond in writing and articulate the basis for its action.

(b) Subsection (a) of this section shall not apply to settlement negotiations between agencies and regulated parties, to notices of a prospective legal action, or to litigation before courts.

(c) An agency may proceed without regard to subsection (a) of this section where necessary because of a serious threat to health, safety, or other emergency or where a statute specifically authorizes proceeding without a prior opportunity to be heard. Where an agency proceeds under this subsection, it nevertheless must afford any person an opportunity to be heard, in person or in writing, regarding the agency's legal determinations and respond in writing as soon as practicable. [Emphasis added].

COUNT V
Declaratory Judgment – Violation of FIFRA

128. Paragraphs 1 through 127 of this Complaint are incorporated by reference, and alleged, as though fully stated herein.

129. This Complaint presents an actual controversy regarding the interpretation of FIFRA as it relates to the scope and limit of EPA's authority to determine that an FDA-approved hand wipe product is a "pesticide," and to issue a recall demand, threaten a SSURO, or take other enforcement action on the basis of such a determination. The dispute is ripe because the EPA refuses to explain, discuss or consider modifying its threat in the August 29, 2020 advisory letter to remove the product from commerce.

130. Pursuant to 28 U.S.C. § 2201(a), to resolve the actual controversies regarding the interpretation and application of FIFRA and the EPA's authority with respect thereto, Tzumi seeks a declaratory judgment, as set forth in the Prayer for Relief, with respect to the duties and obligations of the EPA under FIFRA.

131. FIFRA does not authorize the issuance of a SSURO without a prior finding of a violation of FIFRA and without a showing by the EPA that a SSURO is necessary to combat serious violations and hazards to human health and the environment.

132. The EPA has not made a finding that Tzumi violated FIFRA based on a sufficiently developed record and fair process after notice. In particular, the EPA has not made a finding that "Wipe Out!" is intended or labeled for use other than on the human body. Nor has the EPA shown that the "Wipe Out!" product poses a threat to human health or the environment when used in the manner approved by the FDA.

COUNT VI
Declaratory Judgment – Due Process

133. Paragraphs 1 through 132 of this Complaint are incorporated by reference, and alleged, as though fully stated herein.

134. This complaint presents an actual controversy regarding the interpretation of the Fifth Amendment to the United States Constitution because it relates to the scope and limit of the EPA's authority to demand a recall and issue a SSURO without providing the target of such regulatory actions with notice and an opportunity to be heard.

135. Pursuant to 28 U.S.C. § 2201(a), to resolve the actual controversies regarding the interpretation and application of FIFRA and the EPA's authority with respect thereto, Tzumi

seeks a declaratory judgment, as set forth in the Prayer for Relief, with respect to the constitutionality of FIFRA as applied by EPA to the facts of this case.

136. There is a disputed issue of fact with respect to whether "Wipe Out!" is intended for use other than as a germicide on the human body, which is a drug outside the scope of FIFRA, or is intended for use within the scope of FIFRA. The EPA has not given Tzumi the opportunity to demonstrate that "Wipe Out!" is a drug that is neither intended nor labeled for use as a pesticide.

137. Tzumi's FDA-compliant "Wipe Out!" product is a substantial property within the meaning of the Fifth Amendment to the United States Constitution.

138. The recall demand and threat of a SSURO or similar enforcement action deprive Tzumi of its FDA-compliant "Wipe Out!" product business.

139. EPA failed to afford Tzumi adequate pre-deprivation notice and an opportunity to be heard regarding these regulatory measures.

PRAYER FOR RELIEF

WHEREFORE, Tzumi respectfully requests that this Court enter judgment in its favor, and that this Court enter an Order as follows:

A. Declaring the EPA's recall demand and threatened SSURO requiring Tzumi to either destroy its "Wipe Out!" product or register the product as a pesticide to be arbitrary, capricious and otherwise not in accordance with law in violation of 5 U.S.C. § 706(2)(A);

B. Declaring the EPA's recall demand and threatened SSURO to have been issued *ultra vires* and/or in violation of the requirements of FIFRA and 5 U.S.C. § 706(2);

C. Declaring that the Fifth Amendment to the United States Constitution requires notice and an opportunity to be heard prior to the deprivation of Tzumi's right to sell an FDA-approved product, and accordingly declaring that FIFRA, to the extent it was applied by EPA to deprive Tzumi of its rights without Due Process, is unconstitutional;

D. Declaring that the EPA's attempted change of regulatory direction requires notice to the regulated community, an opportunity to be heard, and a reasonable explanation for the change by the EPA, particularly in light of the regulated community's longstanding reliance on FDA rather than EPA regulation;

E. Declaring that the EPA's attempted change of regulatory direction constitutes unlawful rulemaking in violation of Section 553 of the APA;

F. Declaring that the EPA's attempted change of regulatory direction violates Executive Order 13892;

G. Declaring that Tzumi lacks an adequate remedy at law with respect to, and will suffer irreparable harm as a result of, the EPA's issuance of the recall demand, threatened SSURO, or any other enforcement action that would result in removing "Wipe Out!" from commerce;

H. Declaring that Tzumi cannot, in a suit for damages brought in this Court, recover damages as compensation for the costs, expenses, competitive and other injuries it will suffer as a direct result of actions of the EPA described herein;

I. Setting aside the EPA's recall demand and the threatened SSURO in accordance with 5 U.S.C. § 706(2)(A);

J. Preliminarily and permanently enjoining Defendants from: (i) issuing any SSURO regarding Plaintiff's "Wipe Out!" product, (ii) seizing, recalling, or suspending the sale of Plaintiff's "Wipe Out!" product, (iii) imposing civil penalties in connection with the sale of

Plaintiff's "Wipe Out!" product, (iv) refusing import entry of Plaintiff's "Wipe Out!" product, (v) interfering with Plaintiff's commercial relationships, activities, contracts, vendors and/or distributors regarding Plaintiff's "Wipe Out!" product, or (vi) taking any other enforcement action or entering an Administrative Order that would have an effect substantially similar to the foregoing specified actions; or, in the alternative,

K. Granting the foregoing injunctive relief pending a remand to the EPA for regulatory due process, including but not limited to a hearing to determine whether hand sanitizer products can be considered pesticides based on consumer use, and if so, whether duplicative regulation with the FDA, or taking over regulation from the FDA, is appropriate;

L. Ruling that should the EPA decide after notice and a hearing to assert jurisdiction over hand sanitizer products, such assertion of jurisdiction will not be retroactive.

M. Providing Plaintiff with such other relief as this Court may deem just.

Dated: New York, New York
January 25, 2021

SILLS CUMMIS & GROSS P.C.

By: *s/ Mark S. Olinsky*
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VERIFICATION OF COMPLAINT FOR
DECLARATORY AND INJUNCTIVE RELIEF

I, Isaac Saka, hereby verify under penalty of perjury that I am the Vice President of Tzumi Innovations, LLC and that I am authorized pursuant to applicable law and rules to verify the foregoing First Amended Complaint for Declaratory and Injunctive Relief, that I have reviewed the First Amended Complaint for Declaratory and Injunctive Relief, and that the allegations contained therein are true and correct to the best of my knowledge and information. With respect to communications between Tzumi's counsel and the EPA, I refer to the Declaration of Thomas H. Prol.

Executed on January 25, 2021